



DEPARTMENT OF HEALTH & HUMAN SERVICES

SEP 20 1999

Food and Drug Administration
Rockville MD 20857

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The Honorable Dennis J. Kucinich
House of Representatives
Washington, D.C. 20515-3510

Dear Mr. Kuchinich:

Thank you for your letter of May 17, 1999, concerning actions by the Food and Drug Administration (FDA or the Agency) in regard to labeling of foods treated with ionizing radiation. We apologize for the lengthy delay in responding.

The 1997 FDA Modernization Act (PL 105-115) states that "[n]o provision . . . shall be construed to require on the label or labeling of a food a separate radiation disclosure statement that is more prominent than the declaration of ingredients" FDA published a final rule implementing this provision of the law in the Federal Register of August 17, 1998. A copy of this regulation, along with the pre-existing labeling requirements for food treated with ionizing radiation, Title 21 Code of Federal Regulations, § 179, is enclosed for your information.

In addition, the Statement of Managers accompanying the FDA Modernization Act directed FDA to publish for public comment further proposed changes to the Agency's current labeling regulations. The managers stated their intention that any required labeling be of a type and character such that it would not be perceived to be a warning or give rise to inappropriate consumer anxiety. On February 17, 1999, FDA published an Advance Notice of Proposed Rulemaking (ANPR) in the Federal Register soliciting public comment on whether additional revisions to the current irradiation labeling requirements are needed and, if so, what form such revisions might take. The deadline for comments in response to the ANPR was extended to July 19, 1999.

We have forwarded your correspondence to the Docket for inclusion in the record. FDA's final approach to labeling of

98N-1038

C4744/ANS

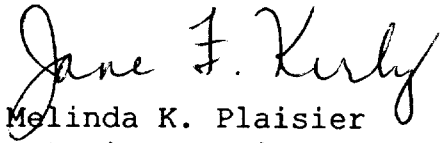
Page 2 - The Honorable Dennis J. Kucinich

irradiated foods will take into account all of the data and information received.

Because your constituent may be concerned about irradiation labeling for meat and poultry, you may also wish to contact the United States Department of Agriculture (USDA) for information. (USDA has primary regulatory authority over meat and poultry products, including the labeling of such products.)

We have also enclosed some general background on the issue of irradiation. We trust this information responds to your concerns. If you have further questions about this or any other matter, please do not hesitate to contact us again.

Sincerely,


for Melinda K. Plaisier
Interim Associate Commissioner
for Legislation

Enclosures

cc: Dockets Management Branch
(98N-1038)

DENNIS J. KUCINICH

10TH DISTRICT, OHIO

1730 LONGWORTH OFFICE BUILDING
WASHINGTON, D.C. 20515
(202) 225-5871

14400 DETROIT AVENUE
LAKEWOOD, OHIO 44107
(216) 228-8850



Congress of the United States
House of Representatives

Committees:
Government Oversight
Education
and the
Workforce

May 17, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

RE: Docket No. 98N-1038, Irradiation in the Production, Processing, and Handling of Food

To Whom It May Concern:

I am writing to urge you to extend the comment period for this Docket past the current end date of May 18, 1999. I would also like express my support for the recommendation by the Center for Science in the Public Interest regarding labeling of irradiated foods.

Despite the fact that the FDA has determined that radiation is safe for food, many consumers do not want to eat foods treated with radiation. Radiation changes the texture, taste, nutritional value, and chemical composition of foods. It also creates a new class of byproducts that have not been tested for their possible carcinogenic and other long-term effects on humans.

The Center for Science in the Public Interest recommends that "any foods, or any foods containing ingredients that have been treated by irradiation, should be labeled with a written statement on the principal display panel indicating such treatment. The statement should be easy to read and placed in close proximity to the name of the food and accompanied by the international symbol. If the food is unpackaged, this information should be clearly displayed on a poster in plain view and adjacent to where the product is displayed for sale."

Like other labels, irradiation labels are required by the FDA to be truthful and not misleading. I believe that the terms "treated with radiation" or "treated by irradiation" should be retained. Any phrase involving the word "pasteurization" is misleading because pasteurization is an entirely different process of rapid heating and cooling.

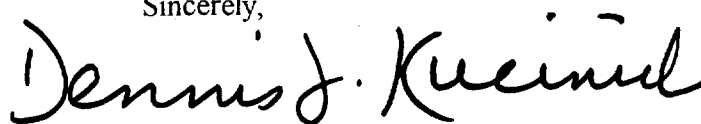
The requirement for irradiation disclosure (both label and radura) should not expire at any time in the future. The material fact of processing remains. Even if some consumers become familiar with the radura, new consumers (e.g. young people, immigrants) will not be. The symbol should be clearly understandable at the point of purchase for everyone. If there is no label, consumers will be misled into believing the food has not been irradiated.

No. 99-4791
98N-1038

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Once again, I believe more time is needed to allow consumers to comment on this issue and urge you to extend the deadline.

Sincerely,

A handwritten signature in black ink, reading "Dennis J. Kucinich". The signature is written in a cursive, flowing style with a large initial "D".

Dennis J. Kucinich
Member of Congress

DJK:jj